UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Isotretinoin

Program	Prior Authorization
Medication	**Preferred Agents:** Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin) **Non-Preferred Agents:** Absorica (isotretinoin)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New York, New York EPP, Rhode Island, Pennsylvania CHIP, New Jersey, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	12/2019
Effective Date	2/2020

1. Background:

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or more. "Severe," by definition, means "many" as opposed to "few or several" nodules. Isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. Due to its severe teratogenicity, isotretinoin is not indicated in females who are or may become pregnant.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, do not initiate it until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

Black boxed warnings include but may not be limited to risk of birth defects.

2. Coverage Criteria:

A. Oncology Uses (off label)

1. **Oral isotretinoin** will be approved based on the following criteria:

   a. Used for oncology indication meeting NCCN or other compendia recommendations per policy

Authorization will be issued for 12 months

B. Acne

1. **Initial Authorization**

   a. **Oral isotretinoin** will be approved based on **all** of the following criteria:

      1. **One** of the following:

         (a) Diagnosis of severe recalcitrant nodular acne unresponsive to conventional therapy

         -OR-

         (b) Diagnosis of treatment resistant acne

      -AND-

      2. History of failure, contraindication, or intolerance to an adequate trial on **two** of the following conventional therapy regimens:

         (a) Topical retinoid or retinoid-like agent [eg,Retin-A/Retin-A Micro (tretinoin)]

         -OR-

         (b) Oral antibiotic [eg, Ery-Tab (erythromycin), Biaxin (clarithromycin), Minocin (minocycline)]

         -OR-

         (c) Topical antibiotic with or without benzoyl peroxide [eg, Cleocin-T (clindamycin), erythromycin, BenzaClin (benzoyl peroxide/clindamycin), Benzamycin (benzoyl

peroxide/erythromycin)]

-AND-

3. If the request is for a non-preferred medication, there must be a reason or special circumstance that the patient must be treated with a non-preferred medication.

Authorization will be issued for 6 months of therapy.

2. **Reauthorization**

a. **Oral isotretinoin** will be approved for **continuation of therapy** based on one of the following criterion:

1. After ≥ 2 months **off** therapy, persistent or recurring severe recalcitrant nodular acne is still present

-OR-

2. Total cumulative dose for total duration of therapy is less than 150mg/kg (will be approved up to a total up 150mg/kg)

Reauthorization will be issued for up to 6 months of therapy.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Absorica Prescribing Information. Ranbaxy Laboratories Inc. Jacksonville FL. May 2018.
2. Amnesteem Prescribing information. Mylan Pharmacetuicals Inc., Morgantown WV. August 2019.
3. Claravis Prescribing Information. Teva Pharmaceuticals USA, Inc., North Wales, PA. May 2018.
4. Myorisan Prescribing Information. VersaPharm Inc., Lake Forest, IL. October 2018.
5. Zenatane Prescribing Information. Dr. Reddy's Laboratories Limited, Princeton, NJ. January 2019.

Program	Prior Authorization –Myorisan (isotretinoin), Claravis (isotretinoin), Amnesteem (isotretinoin), Zenatane (isotretinoin), Absorica (isotretinoin)
Change Control	
Date	Change
9/2009	Criteria were taken from a previously approved Unison policy, RX06 Accutane. Policy was reformatted.
12/2010	Annual Review, no changes.
12/2011	Annual Review, no changes.
12/2012	Annual Review, no changes.
7/2016	Clinical criteria updated to align with E&I notification policy. Updated policy to new template.
9/2016	Added Absorica and non-preferred criteria to policy
7/2017	Annual review. Updated reauthorization duration. Updated references.
9/2017	Added clarithromycin as an example of an oral antibiotic
2/2018	Removed non-preferred criteria since all products are preferred
7/2018	Annual review. Updated references.
5/2019	Added non-preferred criteria. Absorica moving to non-preferred status.
12/2019	Annual review, updated references.